

Serial No.: 10/063,568

Filed: May 2, 2002

Reply to Office Action of June 15, 2004

REMARKS

Initially, Applicants note that on December 13, 2002, Applicants submitted (and the USPTO received) in this application a new power of attorney document (providing the undersigned power to prosecute this application) and a request for a change of correspondence address. In that document, it was requested that all future correspondence be sent to the undersigned attorney at Genentech, Inc., 1 DNA Way, MS49, South San Francisco, CA 94080. Applicants note that the current Office Action, however, was sent to a different mailing address. Applicants respectfully request that all future correspondence for this application be sent to the address requested in the document filed with the PTO on December 13, 2002. A copy of this power of attorney and change of correspondence document (as well as a copy of the return receipt postcard evidencing safe receipt by the USPTO) is enclosed herewith.

Claims 1-6 were pending for prosecution in this application. Applicants have herein amended Claims 1-5 and have canceled Claim 6 without prejudice or disclaimer, wherein support for the claim amendments made herein can be found in the specification at least in the claims as originally filed and at paragraphs 24 and 246.

Applicants have amended the specification so as to properly recognize certain trademarks presented therein, as suggested by the Examiner.

The Rejections under 35 U.S.C. § 101

Claims 1-6 stand rejected under 35 U.S.C. § 101 as allegedly not being supported by either a specific and substantial asserted utility or a well-established utility. Applicants respectfully traverse the rejection.

Initially, Applicants respectfully direct the Examiner to Example 18 starting on page 140 of the current specification which provides an analysis that is useful for identifying molecules that are differentially expressed in human tumor samples as compared to the corresponding normal tissue. With more specific regard to the presently claimed subject matter, the Examiner is respectfully

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directed to the specific data in Example 18 for DNA59610-1556 which demonstrates that that particular molecule is detectably overexpressed in human esophageal tumor as compared to its normal tissue counterpart (i.e., normal human esophageal tissue) and is also detectably overexpressed in human lung tumor as compared to its normal tissue counterpart (i.e., normal human lung tissue). This data is specific for DNA59610-1556 and the polypeptide encoded thereby (i.e., SEQ ID NOS:59 and 60, respectively). Clearly, therefore, these data support the conclusion recited in Example 18 that the “identification of the differential expression of the PRO polypeptide-encoding nucleic acid in one or more tumor tissues as compared to one or more normal tissues of the same tissue type renders the molecule useful diagnostically for the determination of the presence or absence of tumor in a subject suspected of possessing a tumor”. In other words, any of the presently claimed antibodies would be useful as diagnostic probes for the determination of esophageal or lung tumor in human tissue samples of previously unknown morphology. Applicants submit, therefore, that the data presented in Example 18 clearly demonstrates a specific, substantial and credible utility for the presently claimed invention. Applicants, therefore, respectfully request reconsideration and withdrawal of the outstanding rejection.

The Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Cancellation of this claim hereby renders this rejection moot.

The Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1, 2 and 4-6 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly fails to teach how to use the claimed invention based upon the alleged lack of utility described above. Applicants respectfully traverse the rejection.

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With regard to how to “use” the presently claimed antibodies, as described above, Applicants have demonstrated in Example 18 that DNA59610-1556 and the polypeptide encoded thereby are detectably overexpressed in human esophageal and lung tumors as compared to their normal, non-cancerous respective counterpart tissues. Therefore, quantitative determination of the level of expression of the polypeptide of SEQ ID NO:60 in a human tissue sample of unknown pathology is clearly useful for the diagnostic determination of both esophageal and lung cancer in humans. This is clearly described and set forth in the present specification. Techniques for using antibodies as probes for the quantitative measurement of polypeptide expression in a human tissue sample (including, for example, immunohistochemistry and western blotting) are well known and routinely used in the art and are described in detail in the present specification. As such, Applicants respectfully submit that the present specification, taken with what is well known and routinely employed in the art, clearly teaches how to make and use the claimed invention without undue experimentation. It is believed, therefore, that the outstanding rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement is improper and should be withdrawn.

The Rejections under 35 U.S.C. § 102(e)

Claims 1, 2 and 4-6 stand rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by U.S. Patent No. 6,468,546. Moreover, Claims 1-6 stand rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by (a) Chen (U.S. Patent Application Publication 2002/0168762), (b) Ople et al. (U.S. Patent Application Publication 2002/0051990) and (c) Fox et al. (U.S. Patent Application Publication 2002/0165347). Applicants respectfully traverse the rejections.

Initially, Applicants first note that the present application was filed on May 2, 2002 and claims priority to at least PCT/US99/12252, filed on August 24, 2000. In the present Office Action, the Examiner asserts on the record that the presently claimed subject matter has an effective filing date of this PCT application, namely August 24, 2000 (see the present Office Action at page 2, first full paragraph).

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Moreover, Applicants note that the herein cited Chen publication was filed on July 26, 2001 (i.e., after the August 24, 2000 effective priority date of the present application afforded by the Examiner). As such, the Chen reference can only be effective prior art under 35 U.S.C. § 102(e) to the present application if it is entitled to its claimed priority date (i.e., U.S. provisional application serial no. 60/220,991, filed on July 27, 2000). In other words, the Chen reference cannot be anticipating prior art to the present claimed invention unless the priority document claimed by the Chen published application has an anticipating disclosure to the presently claimed invention. As the provisional application to which the herein cited Chen publication claims priority is not available to Applicants and was not provided to the Applicants by the Examiner, it is not possible for Applicants to determine whether Chen is, or is not, entitled to a prior art date which is earlier than their July 26, 2001 filing date. As such, without the Examiner providing such prima facie evidence, Applicants must assume that the effective prior art date of the Chen publication is its filing date, namely July 26, 2001. In this case, therefore, the Chen publication is simply not effective prior art under 35 U.S.C. § 102(e) to the present application. The rejection with regard to the Chen reference, therefore, should be withdrawn.

Additionally, the same situation applies to the herein cited Ople et al. reference. Applicants note that the herein cited Ople et al. publication was filed on June 11, 2001 (i.e., after the August 24, 2000 effective priority date of the present application afforded by the Examiner). As such, the Ople et al. reference can only be effective prior art under 35 U.S.C. § 102(e) to the present application if it is entitled to its claimed priority date (i.e., U.S. provisional application serial no. 60/210,451, filed on June 9, 2000). In other words, the Ople et al. reference cannot be anticipating prior art to the present claimed invention unless the priority document claimed by the Ople et al. published application has an anticipating disclosure to the presently claimed invention. As the provisional application to which the herein cited Ople et al. publication claims priority is not available to Applicants and was not provided to the Applicants by the Examiner, it is not possible for Applicants to determine whether Ople et al. is, or is not, entitled to a prior art date which is earlier than their

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June 11, 2001 filing date. As such, without the Examiner providing such prima facie evidence, Applicants must assume that the effective prior art date of the Ople et al. publication is its filing date, namely June 11, 2001. In this case, therefore, the Ople et al. publication is simply not effective prior art under 35 U.S.C. § 102(e) to the present application. The rejection with regard to the Ople et al. reference, therefore, should be withdrawn.

Finally, the same situation applies to the herein cited Fox et al. reference. Applicants note that the herein cited Fox et al. publication was filed on June 29, 2001 (i.e., after the August 24, 2000 effective priority date of the present application afforded by the Examiner). As such, the Fox et al. reference can only be effective prior art under 35 U.S.C. § 102(e) to the present application if it is entitled to its claimed priority date (i.e., U.S. provisional application serial no. 60/215,645, filed on June 30, 2000). In other words, the Fox et al. reference cannot be anticipating prior art to the present claimed invention unless the priority document claimed by the Fox et al. published application has an anticipating disclosure to the presently claimed invention. As the provisional application to which the herein cited Fox et al. publication claims priority is not available to Applicants and was not provided to the Applicants by the Examiner, it is not possible for Applicants to determine whether Fox et al. is, or is not, entitled to a prior art date which is earlier than their June 29, 2001 filing date. As such, without the Examiner providing such prima facie evidence, Applicants must assume that the effective prior art date of the Fox et al. publication is its filing date, namely June 29, 2001. In this case, therefore, the Fox et al. publication is simply not effective prior art under 35 U.S.C. § 102(e) to the present application. The rejection with regard to the Fox et al. reference, therefore, should be withdrawn.

With respect to the herein cited U.S. Patent No. 6,468,546 reference, the effective prior art date thereof is September 24, 1999 (a date which Applicants note is earlier than any of the priority dates claimed by the Chen, Ople et al. and Fox et al. published applications). As such, the effective 35 U.S.C. § 102(e) date of the U.S. Patent No. 6,468,546 reference is less than a year prior to the August 24, 2000 effective priority date of the present application.

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In light of the above, Applicants enclose herewith a declaration under 37 C.F.R. § 1.131 signed by William I. Wood, Ph.D. (an inventor of the claimed invention) which serves to swear back of the herein cited references, and thereby remove them as references that can be relied upon in support of a rejection under 35 U.S.C. § 102(e). More specifically, Dr. Wood provides facts demonstrating that the present Applicants had conceived of, described and constructively reduced to practice the antibodies of the present invention, before the effective prior art date of the herein cited references. Relevant case law specifically makes clear that such a declaration under 37 C.F.R. § 1.131 is sufficient in this situation to remove the herein cited references as prior art which can be relied upon by the Examiner in support of a rejection under 35 U.S.C. § 102(e).

Relevant Case Law

In support of Applicants conclusion, the Examiner is first respectfully directed to *In re Stempel*, 113 USPQ 77 (CCPA 1957) where the patent applicant (Stempel) had claims directed to both (i) a particular genus of chemical compounds (the “generic” claim) and (ii) a single species of chemical compound that was encompassed within that genus (the “species” claim). In support of a rejection under 35 U.S.C. § 102, the examiner cited against the Stempel application a prior art reference that disclosed the exact chemical compound recited in Stempel’s “species” claim. In response to the rejection, Stempel filed a declaration under 37 C.F.R. § 1.131 demonstrating that he had made that specific chemical compound prior to the effective date of the cited prior art reference. The lower court found the 131 declaration effective to “swear back” of the prior art reference for purposes of allowing a claim to the specific species. However, relying on the doctrine that prior disclosure of a species is sufficient to anticipate a later claim to a genus encompassing that species, the lower court ruled the 131 declaration ineffective for swearing behind the cited references for purposes of the “genus” claim.

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On appeal, however, the CCPA reversed the decision of the lower court and found Stempel's 131 declaration effective for swearing behind the cited reference for purposes of both the "species" claim and the "genus" claim. Specifically, the CCPA stated in support of its decision:

"We are convinced that under the law all the applicant can be required to show [in a declaration under 37 C.F.R. § 1.131] is priority with respect to **so much of the claimed invention as the reference happens to show**. When he has done this he has disposed of the reference." (*Id.* at 81; emphasis supplied).

Thus, the well established "Stempel Doctrine" stands for the clear proposition that a patent applicant can effectively swear back of and remove a cited prior art reference merely by showing that he or she made only that portion of the claimed invention that is disclosed in the prior art reference. In other words, a patent applicant need not demonstrate that he or she made his or her entire claimed invention in order to remove a cited prior art reference under 37 C.F.R. § 1.131.....to the contrary, he or she only need show prior possession of that portion of his or her claimed invention that is disclosed in the prior art reference and nothing more.

Secondly, the Examiner is next respectfully directed to *In re Moore*, 170 USPQ 260 (CCPA 1971), where the Stempel rule was applied to cases where a reference disclosed the claimed compound but no failed to disclose a sufficient utility for it. More specifically, the patent applicant (Moore) claimed a specific chemical compound called PFDC. In support of a rejection of the claim under 35 U.S.C. § 102, the examiner cited a reference which disclosed the claimed PFDC compound, but did not disclose a utility for that compound. Applicant Moore filed a declaration under 37 C.F.R. § 1.131 demonstrating that he had made the PFDC compound before the effective date of the cited prior art reference, even though he had not yet established a utility for that compound. The lower court found the 131 declaration ineffective to swear back of and remove the cited reference, reasoning that since Moore had not established a utility for the PFDC compound prior to the effective date of the cited prior art reference, he had not yet completed his "invention".

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On appeal, however, the CCPA reversed the lower court decision and indicated that the 131 declaration filed by Moore was sufficient to remove the cited reference. The CCPA relied on the established “Stempel Doctrine” to support its decision, stating:

“An applicant need **not** be required to show [in a declaration under 37 C.F.R. § 1.131] any more acts with regard to the subject matter claimed that can be carried out by one of ordinary skill in the pertinent art following the description contained in the reference....the determination of a practical utility when one is not obvious need **not** have been accomplished prior to the date of a reference unless the reference also teaches how to use the compound it describes. (*Id.* at 267, emphasis supplied).

Thus, *In re Moore* confirms the Stempel rule holding that in order to effectively remove a cited reference with a declaration under 37 C.F.R. § 1.131, an applicant need only show that portion of his or her claimed invention that appears in the cited reference. Moreover, *In re Moore* clearly stands for the proposition that when a cited reference discloses a claimed chemical compound either absent a utility or with a utility that is different from the one appearing in the claims at issue, a patent applicant can effectively swear back of that reference by simply showing prior possession of the claimed chemical compound. In other words, under this scenario, the patent applicant need not demonstrate that he or she had discovered a patentable utility for the claimed chemical compound prior to the effective date of the prior art reference.

This premise is also set forward in *In re Rainer*, 159 USPQ 334 (CCPA 1968), where the CCPA stated:

“It is settled, of course, that an anticipatory disclosure, not a statutory bar, may be removed as a reference against a generic claim by a Rule 131 affidavit showing prior reduction to practice of as much of the claimed invention as the reference shows...”

Finally, the Examiner is respectfully directed to *In re Clarke*, 148 USPQ 665 (CCPA 1966), where the patent applicant (Clarke) filed a patent application claiming a genus of chemical compounds. The reference cited against the Clarke application was a publication showing one species falling within the scope of Clarke’s generic claim. In response, Clarke submitted a declaration under 37 C.F.R. § 1.131 demonstrating that he had conceived of the claimed genus of

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chemical compounds and had actually reduced to practice one species of the genus, however, that species was different from the one disclosed in the cited reference. In other words, Clarke was not able to show that he had actually reduced to practice the same chemical compound that was disclosed in the cited prior art reference. Thus, unlike the patent application in the *In re Stempel* case described above, Clarke did not show complete prior possession of the species disclosed in the cited prior art reference. Nevertheless, the CCPA held Clarke's 131 declaration effective if he showed that reduction to practice of the one species was sufficient to substantiate a claim to the whole genus which included the species disclosed in the reference. The CCPA indicated that such substantiation is provided if the reference species would have been obvious to one of ordinary skill in the art in light of what the applicant had completed prior to the invention. Specifically, the CCPA stated:

“the [Stempel] rule for antedating references is not limited to fact situations where the inventor can show priority to the *identical* compound described in the reference...[a]n applicant should not be prevented from obtaining a patent to an invention where a compound described in a reference would have been obvious to one of ordinary skill in the art in view of what the affiant proves was completed with respect to the invention prior to the effective date of the reference....[W]here it can be concluded that facts, offered in a rule 131 affidavit in support of a general allegation of conception and reduction to practice of the invention, would persuade one of ordinary skill in the art to a reasonable certainty that the applicant possessed so much of the invention as to encompass the reference disclosure, then that showing should be accepted as establishing prima facie a case of inventorship prior to the reference.....Upon satisfying that test, **species of the reference falling within the claim may be antedated indirectly.**” (*Id.* at 669-670, emphasis supplied).

Thus, *In re Clarke* makes clear that the Stempel rule described above extends to situations where the specific compound disclosed in the prior art reference is not identical to the compound actually reduced to practice by the patent applicant if (1) those compounds fall within the same genus and (2) the patent applicant demonstrates conception of that genus prior to the effective date of the prior art reference.

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The Present Analysis

Applicants submit herewith a declaration under 37 C.F.R. § 1.131 signed by William I. Wood, Ph.D. (an inventor of the presently claimed subject matter) which serves to swear back of the herein cited references. More specifically, Dr. Wood provides facts demonstrating that the present Applicants had conceived and described in great detail the antibodies of the present claims prior to the effective prior art dates of the herein cited references and, further, had constructively reduced to practice such antibodies prior to the effective prior art date of the herein cited references.

More specifically, the enclosed declaration under 37 C.F.R. § 1.131 by William I. Wood, Ph.D. demonstrates that the polypeptide sequence of SEQ ID NO:60 was conceived of and actually reduced to practice prior to the effective dates of the herein cited references. Moreover, the enclosed declaration under 37 C.F.R. § 1.131 by William I. Wood, Ph.D. further demonstrates that antibodies binding to this polypeptide sequence were conceived of, described in great detail and constructively reduced to practice prior to the effective date of the herein cited references. As such, under the rules set forth by the CCPA in *In re Stempel*, 113 USPQ 77 (CCPA 1957), *In re Moore*, 170 USPQ 260 (CCPA 1971), *In re Rainer*, 159 USPQ 334 (CCPA 1968) and *In re Clarke*, 148 USPQ 665 (CCPA 1966) described above, Applicants respectfully submit that the enclosed declaration under 37 C.F.R. § 1.131 by William I. Wood, Ph.D. serves to effectively remove all of the herein cited references as prior art that can be relied upon by the Examiner in support of a rejection under 35 U.S.C. § 102(e).

In light of the above amendments and remarks, Applicants believe that this application is now in condition for immediate allowance and respectfully request that the outstanding rejections be withdrawn and this case passed to issue.

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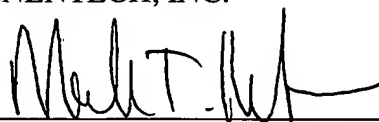
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The Examiner is invited to contact the undersigned at (650) 225-4461 if any issues may be resolved in that manner.

Respectfully submitted,

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